

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

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ENRIQUE GALLARDO
and
MARY R. GALLARDO;

Plaintiff,

-against-

BAYER CORPORATION,
BAYER AG,
GLAXOSMITHKLINE, PLC,
GLAXOSMITHKLINE,
SMITHKLINE BEECHAM

**COMPLAINT
AND JURY
DEMAND**

Defendants.

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Plaintiffs, by their attorneys, WEITZ & LUXENBERG, P.C., complaining of the defendants herein,
respectfully allege to this Court upon information and belief as follows:

JURISDICTION

1. The Court has subject matter jurisdiction over this action pursuant to 28 U.S. C. ' 1332.
The amount in controversy for the plaintiffs exceeds \$75, 000.00, exclusive of interest and costs. It is an
action between citizens of different states.

PARTIES

2. Plaintiffs Enrique Gallardo and Mary R. Gallardo are residents of the State of Texas,
County of Uvalde.

3. Bayer Corporation (herein after referred to as **ABayer Corp.®**) is a Pennsylvania Corporation whose principal place of business and address is 100 Bayer Road, Pittsburgh, Pennsylvania 15205-9741.

4. Bayer AG is a German corporation whose principal place of business is in Leverkusen, Germany, and is authorized to do business and is present in the United States, including Pennsylvania.

5. Bayer Corp. was and/or is merely a branch and/or division of defendant Bayer AG due to common ownership, financial dependency, identity of personnel, failure to observe corporate formalities and other circumstances.

6. Bayer Corporation is a wholly owned subsidiary of Bayer AG.

7. Bayer AG identifies all of its entities/corporations/divisions as the **ABayer Group.®**

8. GlaxoSmithKline, PLC is a United Kingdom Corporation with its principal place of business in the United Kingdom and regularly conducts business in and is present in the Commonwealth of Pennsylvania.

9. GlaxoSmithKline is a Pennsylvania Corporation with its principal place of business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania.

10. SmithKline Beecham Corporation (hereinafter referred to as **ASmithKline Beecham®**) is a Pennsylvania Corporation whose address and principal place of business is 1 Franklin Plaza, Philadelphia, Pennsylvania, 19101.

11. On December 27, 2000, SmithKline Beecham and Glaxo Wellcome merged to form GlaxoSmithKline.

12. Upon information and belief, Baycol is also known as Cerivastatin and Lipobay.

13. Upon information and belief, Baycol was manufactured in Germany.

14. Upon information and belief, some Baycol that was manufactured in Germany was sold in the United States.

15. Upon information and belief, at one time Baycol was a registered trademark of GW USA, Inc.

16. Upon information and belief, Baycol is a registered trademark of GW USA, Inc.

17. Bayer Corporation has listed with the New York Department of State, its Chief Executive Officer, as being Walter Wenninger, PhD., Bayer AG Board of MGMT, Bayerwerk D-51368, Leverkusen, Germany.

FACTUAL BACKGROUND

18. This is an action against the defendants on behalf of the plaintiffs, because Enrique Gallardo was prescribed the drug Baycol, also known as Cerivastatin and Lipobay, and who ingested the prescribed dosage of said drug in accordance with the prescription written by the plaintiff's physicians and the container label prepared by plaintiff's pharmacists, and who was seriously injured.

19. Defendants aggressively promoted and sold hundreds of millions of doses of this medication to hundreds of thousands of persons who had or were thought to have high cholesterol levels.

20. These persons include plaintiff who was wrongly exposed to the harmful effects of Baycol.

21. These harmful effects were known to the defendants at all times relevant to this complaint, but were not communicated and/or were not adequately communicated to the plaintiffs, plaintiffs= physicians, pharmacists, other medical professionals or their facilities (hereinafter, "medical professionals"), and/or the U.S. Food and Drug Administration (hereinafter AFDA@).

22. At the time of the manufacture, promotion and sale of Baycol to the plaintiffs, the defendants possessed detailed technical information that indicated that Baycol caused significant and harmful side effects, including: muscle pain, tenderness and weakness, fatigue, nausea, destruction of muscle tissue, rhabdomyolysis, myoglobinuria, liver damage, and/or liver failure, kidney damage, and/or kidney failure, other health problems, and/or death, and was otherwise extremely hazardous.

23. The defendants concealed this information from plaintiffs and plaintiffs' medical professionals.

24. The defendants publicly represented that Baycol was safe and posed no significant health hazards to consumers.

25. In reality, Baycol can be, and is, highly toxic and presents an unacceptable risk of harm to consumers.

26. The defendants also unnecessarily put at risk and wrongfully caused plaintiffs harm without full, proper, and/or timely disclosure, and/or warning of the potential associated risks, hazards, and/or benefits in a truthful way, and/or otherwise acted in such a way as to be negligent, reckless, and as otherwise described in this complaint, liable to plaintiffs.

27. Plaintiffs have suffered damages proximately resulting from the defective nature of Baycol and defendants' conduct.

28. The defendants were in the business of manufacturing and promoting, marketing, researching, distributing and selling prescription medications and non-prescription drugs (hereinafter "marketed"), including Baycol, in the State of Pennsylvania.

29. Plaintiff was prescribed and began taking Baycol subsequent to the time it was introduced

to the United States.

30. Prior to the intake of the aforementioned Baycol, plaintiff was diagnosed as suffering from high cholesterol levels, but were otherwise in reasonably stable health.

31. As a result of taking of defendants' Baycol, plaintiffs suffered damages and injuries. These damages include, but are not limited to, pain, suffering, loss in quality of life, loss of earnings and diminution in earning capacity, loss of society and comfort, loss of consortium, and expenses for reasonable hospital, nursing, and medical services.

32. At the time that the defendants promoted Baycol, there existed five (5) other drugs known as statins available in the United States to treat high cholesterol.

33. The reason that Baycol was marketed by the manufacturing defendants was to make a profit.

34. The defendants, individually and jointly, aggressively took action to accelerate Baycol for approval by the FDA.

35. By July, 1997, the defendants had fraudulently, negligently, recklessly and/or otherwise in bad faith and in violation of their responsibility to the consuming public and their medical professionals, secured FDA approval for Baycol.

36. The defendants marketed Baycol from February 1998 until August 2001, at which time the drug was withdrawn by Defendants from the United States market.

37. The FDA approved of and supported the withdrawal of Baycol.

38. Prior to 1998, and at times subsequent, the defendants had knowledge of Baycol's potential to cause: muscle pain, tenderness and weakness, fatigue, nausea, myoglobinuria, muscle tissue

destruction, kidney damage, liver damage, kidney failure, liver failure, rhabdomyolysis, other injuries, illnesses and conditions, and/or death.

39. Months prior to the recall of Baycol, British regulators had already banned certain dosage levels of Baycol. Japan had also limited sales of Baycol to .3mg. or less, and the FDA considered a similar reduction in Baycol doses available in the United States.

40. Many Baycol related injuries, illnesses and fatalities occurred with the introduction of Baycol's .8mg. dose in August of 2000.

41. After deaths related to Baycol were reported, defendants instructed salesmen to not give away samples of the .8mg. dose.

42. Deaths from Baycol have been related to .4 mg. and .8mg. doses of Baycol alone as well as when Baycol was used simultaneously with Gemfibrozil, another cholesterol-reducing medication.

43. Since 1987 it has been known that Statins, the name for the class of cholesterol reducing medications which includes Baycol, can cause muscle pain and tenderness, as well as kidney and liver damage, kidney and liver failure, as well as Rhabdomyolysis-a painful, life-threatening condition where muscle tissue is destroyed, and travels through the blood stream. Progressive cases cause kidney damage and can lead to kidney failure, renal failure and death.

44. Reports of severe rhabdomyolysis were reported 10 times as frequently with Baycol use as opposed to other cholesterol reducing medications.

45. Fatal Rhabdomyolysis with Baycol is reported when Baycol is used alone, in higher doses, by elderly patients and when used simultaneously with Gemfibrozil, also known as Lopid. Symptoms include: Muscle pain, weakness, tenderness, malaise, fever, dark urine, nausea and vomiting. The pain

may involve specific groups of muscles or may be generalized throughout the body. Often in the muscles of the calves and lower back, but some victims have no muscle injury. Sometimes the injury is so severe that renal failure and/or organ failure follows, and can lead to death.

46. The defendants also had knowledge of other related health problems and potential problems including nausea, fatigue, loss of strength and mobility in upper and lower extremities, liver damage, kidney damage, irreversible liver and kidney failure, and/or death.

47. Since 1999 Bayer and the FDA knew of increased occurrence of illness and/or death when Baycol and Gemfibrozil, another cholesterol reducing medication, were used simultaneously.

48. Prior to presenting the matter to the FDA, defendants had failed to conduct sufficient, necessary and/or appropriate studies regarding the safety and efficacy of Baycol, and/or conducted studies that would be sufficient but Defendants suppressed or modified information from such studies.

49. Despite this fact, defendants represented the contrary to the FDA, the National Institute of Health (hereinafter ANIH®), the consuming public and medical professionals.

50. Based on the studies conducted the defendants knew or should have known that Baycol posed serious and potentially dangerous and life threatening hazards to persons to whom it would be prescribed.

51. Moreover, after knowing that Baycol was harmful to health and could cause life-threatening illness to persons who consumed it, defendants through their agents and employees, continued to promote the use of Baycol to physicians who would be prescribing the drug to persons such as plaintiffs and the members of the public. They failed to adequately and timely inform the consuming public, federal authorities, the FDA and/or medical professionals.

52. The defendants engaged in conduct designed to corrupt the approval process for Baycol and generally defraud the FDA and the consuming public, including the plaintiffs .

53. As part of, and subsequent to, its highly promoted release to the consuming public in February of 1998, the defendants had knowingly, intentionally, fraudulently, negligently, recklessly and/or otherwise in bad faith and in violation of their duties to the consuming public and the plaintiffs, touted Baycol as virtually free of side effects, despite the fact that defendants' own research indicated that Baycol users were significantly more likely to suffer muscle tissue pain and destruction, rhabdomyolysis, liver injury and/or failure, kidney injury and/or failure and death.

54. Statements from the defendants relating to Baycol were later found to be inaccurate, incomplete, and/or false and misleading by federal regulators. The FDA has issued numerous warnings concerning the danger of Baycol, since its approval of the drug, which was based on statements made to it by the defendants.

55. The defendants actively concealed the dangers relating to Baycol from the plaintiffs, the FDA, the world-wide consuming population of high cholesterol medicating patients and medical professionals.

56. The plaintiffs did not know and were not made aware of the full extent of the risks and dangers associated with Baycol. The defendants intended to deceive the consuming public, medical professionals and the plaintiffs into believing that Baycol was safe, when it knew or should have reasonably known the true nature and extent of the serious side effects. The defendants failed to provide adequate warnings to the plaintiffs and/or plaintiffs' physicians and other medical professionals, regarding these dangerous side effects. In fact, the defendants warranted and represented that the risks of Baycol

outweighed the benefits and that the drug was safe.

57. Had the plaintiffs known of the full extent of the risks and dangers associated with Baycol, the plaintiff would not have taken Baycol.

58. On February 18, 1998, Bayer Corporation, Pharmaceutical Division and SmithKline Beecham announced the launch of Baycol. The initial production was at the .2 and .3 mg. dosage. Baycol was similarly released in Canada in March of 1998.

59. On May 26, 1999 the FDA approved a .4 mg. dose of Baycol.

60. The FDA approval of the .4 mg. Baycol dose was based on data provided from 2 studies performed with patients over 8 weeks. Doses lower than .4 mg. were recommended for patients with significant renal impairment.

61. The Department of Health & Human Services, Division of Drug Marketing, Advertising and Communication (DDMAC) objected to Bayer Corporation's promotional material for Baycol in an October 25, 1999 letter. The DDMAC's objections included allegations of :

- misleading claims that Baycol is superior to other statins because of its synthetic makeup;
- misleading claims as to enzyme inhibition;
- overstating the efficacy of Baycol;
- failure to effectively present information regarding side effects and contraindications; and
- inadequate disclaimers and footnotes.

62. In December of 1999 the first deaths were reported due to rhabdomyolysis in Baycol patients.

63. On July 24, 2000, the FDA approved the .8 mg. dose of Baycol.

64. On May 21, 2001, Bayer issued a letter to Health Care Professionals regarding:

a. Voluntary changes to prescribing information for Baycol, specifically revising the **Dosage and Administration** section to **highlight** that .4 mg. is the starting dose for Baycol (1 time per day).....[o]nly patients requiring further lipid adjustment should be titrated to .8 mg. Lower doses were recommended for patients with significant renal impairment.

b. Bayer added a section to the **Warnings-Skeletal Muscle** section reinforcing the .4 mg. start dose stating that **Beginning** therapy above .4 mg. ...increases the risk of myopathy and rhabdomyolysis.

c. The **Patient Information** section states **If** you are taking Baycol for the first time, your daily dose should be .4 mg. or lower.

The correspondence was insufficient to achieve its purpose. It was not complete, did not contain sufficient detail to accomplish its so-called purpose of providing timely and complete disclosure to medical professionals of what the defendants knew and was not otherwise designed to capture the attention of its audience.

65. On August 8, 2001 Bayer issued another letter to Health Care Professionals reporting increased cases of rhabdomyolysis in Baycol users compared to users of other similar medications **especially** when gemfibrozil is co-prescribed...(and) at the .8 mg. dose of Baycol alone. The correspondence was insufficient to achieve its purpose. It was not complete, did not contain sufficient detail to accomplish its so-called purpose of providing timely and complete disclosure to medical professionals of what the defendants knew and was not otherwise designed to capture the attention of its audience.

66. On August 8, 2001, Bayer withdrew Baycol from the US market following reports that at least 32 deaths in the United States from rhabdomyolysis were related to the use of Baycol. Incidents of Rhabdomyolysis had been reported with use of other cholesterol medications, however, fatal cases were reported at a significantly higher rate with Baycol.

67. Bayer's letter to patients briefly stated that Bayer is pulling Baycol, mentioning increased reports of Rhabdomyolysis, particularly when used with gemfibrozil, and added that A[i]f you have been treated successfully with Baycol/Lipobay in the past (and not in combination therapy with gemfibrozil), there is no reason for you to be concerned.@ The correspondence was insufficient to achieve its purpose.

It was not complete, did not contain sufficient detail to accomplish its so-called purpose of providing timely and complete disclosure to plaintiffs and/or medical professionals of what the defendants knew and was not otherwise designed to capture the attention of its audience.

68. The recommended changes and the reasons for the announcement were known to the defendants for an extensive period of time prior to May 21, 2001 and well before Baycol's recall on August 8, 2001. Therefore, the defendants did not timely, fully and adequately provide notice to or otherwise fulfill its duty to the plaintiffs, the consuming public and medical professionals.

69. The defendants' singular motive in their aggressive promotion of Baycol was profit. Baycol was one of Bayer Corp.'s biggest selling prescription drugs, being used by approximately 6 million people, generating over 500 million dollars in sales in the year 2000 alone. Baycol's sales were projected to increase by another 50% to over 800 million dollars for 2001.

70. No adequate notice or warning to plaintiffs, prescribing physicians, the consuming public and/or medical professionals was given by the defendants on these issues.

71. GlaxoSmithKline/SmithKline Beecham promoted, marketed and distributed Baycol in the United States before and since its release in 1998.

72. Bayer Corp. promoted, marketed and distributed Baycol in the United States before and since its release in 1998.

73. Prior to the merger of SmithKline Beecham with GlaxoWellcome into defendant GlaxoSmithKline, as a result of defendant GlaxoSmithKline's due diligence and other research and investigation of SmithKline Beecham, defendant GlaxoSmithKline knew or should have known of all the aforementioned conduct by SmithKline Beecham.

74. As a result of the merger of SmithKline Beecham and Glaxo Wellcome into defendant GlaxoSmithKline, as alleged in paragraph 11 above, defendant GlaxoSmithKline assumed and/or is otherwise liable for all of the aforementioned conduct by SmithKline Beecham.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

75. Plaintiffs adopt by reference the allegations contained and set forth in paragraphs 1 through 74 herein.

76. The defendants did not and/or refused to make to the consuming public and medical professionals, timely and full disclosure in a manner reasonably calculated to reach all persons taking Baycol, including the plaintiffs and all physicians prescribing Baycol, the full extent and nature of the attendant risks and known or reasonably known dangers of taking Baycol. The Defendants failed to maintain a contemporaneous database of prescribing physicians and/or persons to whom Baycol caused injury or death. The defendants failed to report contemporaneously instances of injury or death caused

by Baycol. The defendants failed to follow through on efficacy and safety of Baycol studies and report same to the FDA. This was true despite the fact that lingering safety and effectiveness questions existed. The inherent defects of the bad drug, Baycol are latent and self-concealing. Even in the exercise of reasonable care, the plaintiffs simply could not have discovered that such inherent defects existed. By suppressing the dissemination of information regarding the hazards, dangers and attendant risks of taking Baycol, the defendants intentionally foreclosed plaintiffs from learning of Baycol's latent defects. This foreclosure continues through this date.

77. Any applicable statutes of limitations have been tolled by the defendant's acts of fraudulent concealment and denial of the facts alleged in this complaint. Such acts of fraudulent concealment include: a) knowingly, intentionally and/or recklessly covering up and refusing to disclose internal documents, b) failing to disclose that Baycol was inherently dangerous; and c) misrepresenting the character, quality and nature of Baycol in order to deceive consumers, their physicians and medical professionals, including the releasing of reports which purported to conclude that Baycol was safe. Through such acts of fraudulent concealment the defendants were able to conceal from the public, their physicians, medical professionals, the FDA, and the National Institute of Health, the truth about Baycol's defects, thereby tolling the running of any applicable statute of limitations. The plaintiffs could not reasonably have discovered the true facts of Baycol's danger, the full extent of the truth having been fraudulently and knowingly concealed by the defendants from the date it was first released to a consuming public and/or to medical providers and/or their facilities, through the present date.

78. Furthermore, the defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Baycol. The defendants were

under a duty to disclose the true character, quality and nature of Baycol because this was non-public information over which the defendants had and continue to have exclusive control, and because the defendants knew that this information was not available to the plaintiffs, medical providers and/or to their facilities. In addition, the defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

79. The plaintiffs had no knowledge that the defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the defendants, the plaintiffs could not have reasonably discovered the wrongdoing at any time prior. Also, the economies of this fraud should be considered. The defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiffs and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the defendants' representations.

COUNT I

FRAUD

80. The plaintiffs hereby adopt, repeat and reallege and incorporate by reference herein the allegations contained and set forth in paragraphs 1 through 79.

81. Defendants' representations through national advertising, promotional campaigns, standardized package inserts, related materials, purchased or subsidized so-called expert opinions both orally and in print and in correspondence to healthcare professionals, and in submissions and reports to the FDA, and product information regarding the characteristics of and the quality of Baycol, were false,

misleading, outdated, materially incorrect in fact, and were made knowingly, intentionally, and/or willfully to deceive without regard to the safety and use of the product and were acted on in reasonable reliance by plaintiffs, plaintiffs= prescribing physicians and medical professionals, to plaintiffs= substantial detriment and injury.

82. Defendants= representations as set forth above regarding the quality and characteristics of Baycol were willful and/or reckless misrepresentations of material fact made with the intent to induce plaintiffs and plaintiffs did, without knowledge of their falsity, directly or indirectly justifiably act upon those willful misrepresentations to plaintiffs= injury, as evidenced by plaintiffs= purchase and consumption of Baycol.

83. Defendants either knew or should have known that Baycol was dangerous and not as effective for its purpose as represented, and posed greater risks than disclosed.

84. Defendants were under a duty to disclose this information to the plaintiffs under laws requiring it not to engage in false and deceptive trade practices, and as otherwise alleged in this complaint, because defendants made representations and partial disclosures concerning the nature and quality of their product which they had a duty to correct, because defendants were in a superior position to know the true state of the facts about the dangerous and defective nature of Baycol and its known risks to the plaintiffs and because the defects of Baycol were latent. These intentional representations suppressed and/or concealed material facts, including but not limited to:

- a. suppressing and/or mischaracterizing the known risks to health and effectiveness;
- b. failing to timely and fully disclose the results of tests and studies on the risks

to health and effectiveness;

c. failing to disseminate adequate warnings which would disclose the nature and extent of the side effects of the product, the risks to health, and effectiveness;

d. failing to disclose that adequate and/or standard and/or generally accepted standards for pre-clinical testing had not been done;

e. failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done;

f. failing to disclose that alternative products and methods available posed less risk than Baycol and were at least as effective;

g. failing to conduct adequate tests and studies on the product prior to marketing and making representations as set forth in this complaint;

h. failing to reveal the full nature and extent of the known risks and hazards associated with Baycol; and

i. as otherwise described in this complaint, to be discovered during this litigation and to be proven at trial.

85. As a direct and proximate result of the defendants' fraud, plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical, hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled to under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and

punitive damages.

COUNT II

NEGLIGENCE

86. Plaintiffs herein incorporate by reference as if fully set forth herein each and every allegation set forth in paragraphs 1 through 85. Plaintiffs, in the alternative, plead that the acts described as intentional, deliberate, outrageous, or knowing were instead negligent and/or reckless.

87. The defendants are liable because they breached their duty to the plaintiffs. They were negligent and/or reckless in the licensing, testing, design, manufacture, packaging, warning, advertising, promotion, distribution, representation before the FDA and NIH, and in the sale of Baycol. Said negligence and/or recklessness includes, but is not limited to:

a. manufacturing, compounding, testing, inspecting, packaging, labeling, distributing, marketing, examining, selling and preparing said drug in such manner that it would avoid the risk of injury to the health of users when Baycol was being used in the treatment of high cholesterol levels;

b. manufacturing, compounding, testing, packaging, labeling, and distributing Baycol which was unsafe when it reached the hands of consuming public and medical professionals, including the plaintiffs;

c. failing to warn and/or to adequately warn medical professionals and the consuming public of all of the risks associated with the use of said drug;

d. failing to warn the consuming public directly and through their prescribing

physicians and medical professionals, of the unreasonably dangerous defects associated with said drug after said defendant had knowledge of the same thereby breaching the continuing duty to warn;

e. failing to accompany the product with proper, adequate, necessary and timely warnings regarding the possible adverse side effects associated with the use of Baycol and the comparative severity and duration of such adverse effects. The warnings given by the manufacturer did not accurately reflect the symptoms, scope and severity of the side effects known or which should have been reasonably known at the time;

f. providing adequate training and/or warnings to medical professionals for the appropriate use of Baycol;

g. warning plaintiffs and medical professionals prior to actively encouraging the sale of Baycol either directly or indirectly, orally or in writing, about the following:

- i. the need for comprehensive regular monitoring to assure early discovery of potentially serious side effects;
- ii. the possibility of becoming seriously ill, injured, disabled or killed as a result of the drug's use and/or having to undergo liver surgery, kidney surgery, dialysis treatment, extensive physical therapy, and/or to have serious side effects involving the liver, kidney, and skeletal muscle tissues;
- iii. that liver enzymes may become dangerously high and may result in permanent injuries;

- iv. the potential for serious kidney injury, kidney failure and the need for kidney dialysis treatment;
- v. the potential for suffering serious muscle damage and possibility for extensive physical therapy treatment;
- vi. the potential for developing rhabdomyolysis and/or myoglobinuria as a result of muscle tissue damage; and,
- vii. the nature and extent of adequate medical testing during the use of Baycol;
- h. failing to adequately test and/or warn about the serious side effects of Baycol;
- i. failing to include adequate warnings with the product that would alert consumers, medical professionals and other users to the potential risks and the nature, extent, scope, severity and duration of the serious side effects of Baycol;
- j. failing to inform the FDA and/or the NIH in a timely manner of new information as they became aware of it regarding the potential risks and the nature, extent, scope severity and duration of the serious side effects of Baycol;
- k. continuing to promote the efficacy and safety of the product while providing inadequate warnings and failing to disclose the full extent of the known risk of liver damage, kidney damage, muscle tissue damage, and/or death of which the defendants knew; and;
- l. delaying warnings of and then failing to provide adequate warnings about liver damage and/or failure, kidney damage and/or failure, muscle tissue damage and other health problems and/or death which may have dissuaded medical providers from prescribing the product and depriving the medical providers from weighing the true risks against the benefits of prescribing the Baycol;

88. The defendants knew or should have known that Baycol caused unreasonably dangerous side effects which many users would be unable to remedy by any means and that there were safer alternative methods for the treatment of high cholesterol levels, but continued to overstate the benefits of Baycol and understate the attendant risks and continue to aggressively market and promote Baycol to the consuming public and medical professionals.

89. Agents, servants, consultants, experts and employees of the defendants: Bayer Corporation; Bayer AG; GlaxoSmithkline; GlaxoSmithkline, PLC and SmithKline Beecham engaged in the manufacture, marketing, promotion and distribution of Baycol to plaintiffs and others in the United States, knew or should have known that the Baycol which they marketed and sold was defective and unreasonably dangerous.

90. Said defendants were obligated to use reasonable means and efforts to ascertain the truth of the representations that they were making to medical professionals and others in their marketing campaign and product information, and said defendants failed to use ordinary and reasonable care to communicate the dangers to the prescribing physicians.

91. The defendants, and each one individually, are liable to the plaintiffs for their negligence and/or recklessness.

92. As a direct and proximate result of the negligence and/or recklessness of the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, caused plaintiffs to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well loss of earnings,

diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demands all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT III

FAILURE TO WARN-STRICT LIABILITY

93. The plaintiffs hereby adopt and incorporate herein the allegations contained and set forth in paragraphs 1 through 92.

94. Bayer Corporation, Bayer AG, GlaxoSmithKline, GlaxoSmithKline PLC and SmithKline Beecham at all times relevant hereto, were engaged in the marketing, promotion, formulation, manufacture, marketing, distribution and sale of Baycol. Said defendants are strictly liable in tort to the plaintiffs for reasons including, but not limited to, the following:

a. Baycol was defective, unsafe and unreasonably dangerous for its intended and/or foreseeable uses.

b. a. In formulating, manufacturing, distributing and prescribing a drug in such an unreasonably dangerous condition that it was likely to cause harm to users thereof when being used for its intended purpose.

c. In distributing, promoting and selling Baycol not accompanied by adequate warnings of the danger that were known or should have been known and by violating their duty and obligation to provide adequate warnings of the dangers known or which should have been known to physicians who would be prescribing Baycol to the plaintiff. The product was unaccompanied by proper warnings regarding all known or reasonably knowable potential side effects associated with the use of Baycol, and the comparative nature, extent, severity, incidence and duration of such

adverse effects. The warnings given did not accurately reflect the signs, symptoms, incidence, scope or severity of the side effects, and/or identify appropriate testing, monitoring and/or remedial action. The defendants negligently failed to communicate to prescribing medical professionals in a timely manner information necessary for their purposes, thus placing the consuming public at risk.

d. The defendants failed to perform adequate testing that would have revealed that Baycol possessed serious potential side effects. They also failed to monitor the situation as it developed. As a result of this failure, full and proper warnings were not made that would have accurately and fully reflected the symptoms, scope and severity of this drug.

e. Each of the defendants were aware that Baycol, which was manufactured and supplied by the defendants, would be used without inspection and study for the defects inherent in Baycol as alleged, and that given the resources of the consuming public and their medical professionals, any reasonably anticipated inspection would have failed to detect the defects.

f. Each of the defendants expected and knew that Baycol would reach the consumers and their medical professionals. Baycol was, in fact, received by the plaintiff and medical professionals without change in the condition in which the drug was first manufactured and sold.

g. The plaintiff was a foreseeable user of the product and used the product in its intended manner and suffered serious harm and injury because of said use.

95. The Baycol manufactured and/or supplied by the defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the defendants knew or should have known of the risks of injury from Baycol, they failed to provide adequate warnings to consumers of the

product and continued to aggressively promote Baycol and in doses higher than initially approved by the FDA.

96. As a direct and proximate cause of the defective condition of Baycol as manufactured and/or supplied by the defendants and as a direct and proximate cause of their negligence, carelessness, and/or other wrongdoings and actions as described herein, plaintiffs suffered and will continue to suffer injury, harm, and economic loss.

97. Based on information and belief, the defendants knew of Baycol's defective nature, but continued to design, market, promote, manufacture and sell Baycol so as to maximize sales and profits at the expense of the health and safety of the consuming public and with conscience disregard of foreseeable harm.

98. The defendants, as pharmaceutical manufacturers and sellers, had a duty to warn of adverse drug reactions which it knows or has reason to know, are inherent in the use of its pharmaceutical products.

99. Prior to 1997 and/or through the date it was withdrawn from the U.S. market, the defendants knew or should have known of the risks related to Baycol, including, but not limited to, those specifically stated in this complaint.

100. In light of this knowledge, the defendants had a duty to warn prescribing physicians and consumers, of the known or suspected risks of Baycol arising from its use.

101. The defendants were negligent in the manufacturing, marketing, promotion and sale of the Baycol purchased by the plaintiff, including, but not limited to, the following:

- a. failing to warn prescribing physicians or consumer patients of the actual and

known risk of suffering injury to the liver, suffering injury to the kidneys, suffering injury to the muscle tissues, and/or otherwise suffering injury or death inherent in the use of this product;

b. failing to adequately warn prescribing physicians or consumer patients of the early symptoms of injury to the liver, kidneys, muscle tissue and/or other injuries inherent in the use of this product, the risk of which was known or reasonably should have been known, to be greater than the defendants' writings, inserts and promotions represented;

c. failing to fully disclose to the FDA its knowledge and the nature and extent of known problems with regard to injury to the liver, kidneys, muscle tissue and/or other injuries inherent in the use of this product, including the risk of death, the risks of which were known or reasonably should have been known, to be greater than what was represented in its writings, inserts and promotions represented; and

d. promoting use of Baycol in an aggressive and fraudulent manner, despite evidence against the representations that the defendants made as to its safety, effectiveness and its association with injury to the liver, kidneys, muscle tissue, and/or other injuries, and the risk of death inherent in the use of this product.

102. As a direct and proximate result of the negligence and negligence per se of the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages

to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT IV

DEFECTIVE DESIGN - STRICT LIABILITY

103. The plaintiffs hereby adopt and incorporate herein the allegations contained as set forth in paragraphs 1 through 102.

104. The Baycol manufactured and/or supplied by the defendants was placed into the stream of commerce in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with the design or formulation.

105. The Baycol manufactured and/or supplied by the defendants was placed into the stream of commerce with a defective design or formulation because it was unreasonably dangerous and more dangerous than an ordinary consumer would expect, and more dangerous than other forms of treatment for reducing cholesterol levels.

106. As set forth in this complaint and otherwise, the defendants knew of Baycol's defective nature, but continued to design, manufacture, market, promote, represent to the consuming public, pharmacies, their prescribing physicians, and the medical and general public that Baycol was safe for the sole purpose of maximizing sales and profits at the expense of the public health and safety in conscience disregard of the foreseeable harm caused by Baycol.

107. As a direct and proximate result of the defendants' actions and/or inactions as set forth in

this complaint, plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT V

BREACH OF IMPLIED WARRANTY

108. Plaintiffs herein incorporate by reference as if fully set forth herein each and every allegation contained in paragraphs 1 through 107.

109. At all times material hereto, the defendants marketed, sold and distributed Baycol and knew and promoted the use for which the aforesaid drug was being used by plaintiffs and medical professionals, and impliedly warranted to plaintiffs that the aforesaid medications were of merchantable quality and safe for their intended use.

110. The Plaintiffs and medical professionals reasonably relied on the skill, expertise and judgment of the defendants and their representations as to the fact that Baycol was safe for its intended use and of merchantable quality.

111. The Baycol manufactured and supplied by the defendants was neither safe for the intended use nor of merchantable quality, as warranted by these defendants in that the drugs had dangerous and life threatening side effects.

112. The defendants breached their implied warranty of merchantability in that Baycol is

defective and not fit for the ordinary purpose it is used; the treatment of high cholesterol levels.

113. As a direct and proximate result of the defendants' breach of warranty, the plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT VI

BREACH OF EXPRESS WARRANTY

114. Plaintiffs herein incorporate by reference as if fully set forth herein each and every allegation contained in paragraphs 1 through 113.

115. Defendants expressly warranted that Baycol was safe for its intended use and as otherwise described in this complaint. Baycol did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects and as otherwise set forth in this complaint and/or in the defendants' materials. As previously alleged, notice has been presented to the defendants. This breach of express warranty claim is asserted under 15 U.S.C. 2310(d)(1), or alternatively, to any extent that the Magunson-Moss Act is found inapplicable, under UCC 2-313(2)(c), and/or for breach of contract.

116. As a direct and proximate result of the defendants' breach of warranty, plaintiffs were

caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT VII

NEGLIGENCE *PER SE*

117. Plaintiffs herein incorporate by reference as if fully set forth herein each and every allegation contained in paragraphs 1 through 116.

118. Defendants have an obligation not to violate the law.

119. Defendants have violated the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et. Seq.*, related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws.

120. Plaintiff, as purchaser and consumer of Baycol, and spouse of the Baycol user are within the class of persons the statutes described above are designed to protect. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint is the specific type of harm these and other statutes are designed to prevent.

121. Defendants are responsible to plaintiffs for injuries incurred for their violations of the statutes described above under the doctrine of negligence *per se*.

122. As a direct and proximate result of the negligence and negligence *per se* of the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT VIII

LOSS OF CONSORTIUM

123. Plaintiffs herein incorporate by reference as if fully set forth herein each and every allegation contained in paragraphs 1 through 122.

124. Plaintiff Enrique Gallardo married Mary R. Gallardo prior to the use of Baycol.

125. Enrique Gallardo and Mary R. Gallardo were married at the time of Enrique Gallardo's use of Baycol and were married at all relevant times herein.

126. As a direct and proximate result of the defendants' wrongdoing as set forth in this Complaint, plaintiff Mary R. Gallardo, was caused to suffer a loss of consortium and will continue to suffer a loss of consortium.

COUNT IX

PUNITIVE DAMAGES

127. Plaintiffs herein adopt and incorporate herein the allegations contained and set forth in

paragraphs 1 through 126.

128. Defendants conduct in manufacturing, marketing, selling, distributing, testing and submitting for FDA approval was outrageous, that is, done with bad motives and/or with a reckless indifference to the interest of others, including plaintiffs, the consuming public, health care professionals and the FDA.

129. As a direct and proximate result of the defendants' outrageous conduct, plaintiffs were caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demand all damages to which plaintiffs are entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against each defendant individually and/or jointly for compensatory damages and punitive damages together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

DEMAND FOR A JURY TRIAL

Demand is hereby made for a trial by jury.

Dated: Cherry Hill, NJ
May 23, 2002

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